INDEX

Sr No	Topic	Page
1	INTRODUCTION	3
2	STATEMENT OF PROBLEM	4
3	REVIEW OF LITERATURE	5
4	THEORETICAL CONSTRUCT	9
5	OBJECTIVES OF THE STUDY	11
6	HYPOTHESIS OF THE STUDY	12
7	RESEARCH METHODOLOGY	13
8	SIGNIFICANCE OF STUDY	16
9	SCOPE OF STUDY	17
10	LIMITATIONS OF STUDY	17
11	TENTATIVE CONCLUSION	18
12	REFERENCES	19

1. INTRODUCTION

Over-the-counter medicine is also known as OTC or nonprescription medicine. All these terms refer to medicine that you can buy without a prescription. India's OTC drugs market was worth $6.38 billion in 2019, with an estimated CAGR of 19.4 per cent. The market holds evident potential to reach 15.48 billion by 2024.[1] For the purpose of the current study, OTC medicines have been calssified as follows:

- Cough, Cold, and Flu Products
- Analgesics
- Dermatology Products
- Gastrointestinal Products
- Vitamins, Minerals, and Supplements (VMS)

Storing, transferring, capturing real-time data has become even more essential so that the complex supply chain which is continuously evolving can be managed properly. Due to the pandemic, there was an increase in demand for certain OTC medications, and then there was also an increase in hospitalizations, which has drained the supply of medicines in general. Patients have always been looking to stock up, and that's a normal reaction — that's been another reason for the shortages. And then sometimes, there have also been cases of slower manufacturing times due to labor shortages in some of the areas that have been harder hit. However, the pandemic situation is getting resolved gradually and soon, with the right kind of governmental interventions, the global impact that the pandemic had on the the overall movement of people and goods will get minimized. [2]

To generate common understanding, compliance and visibility, companies can use policies to standardize asset data. Like any other supply chain, OTC pharmaceuticals are extremely vulnerable to contamination, theft, counterfeiting and tampering. And the products and components passed through multiple locations and countries, provenance authenticity is critical. This should be complete end-to-end visibility of inventory, and people should not miss their doses due to the flaws in the supply chain. Organizations must manage the last-mile delivery OTC Medicine supplies.T

Though the batches of OTC medicines are being serialized for easy identification, there is a need to ensure proper proof of pickup and delivery and authenticated chain of custody. To ensure this, the concept of supply chain 4.0 can be applied by using various IoT devices and other applications to make the supply chain visible to all the key supply chain managers. They would be able to trace the source of any intervention that is authorized. Any person who comes into contact with the OTC medicnies must be trained to identify counterfeits, and comprehensive assessment and monitoring must be implemented.

The current study proposes to suggest a model that can be implemented at least at the regional level to make supply chain management more effective and efficient concerning the distribution of OTC drugs. The current study aims to study the impact of supply chain 4.0 on predictive business intelligence (Predictive business intelligence means using artificial

intelligence, machine learning, asset tracking and social media intelligence applications to produce accurate, statistics-based demand forecasts that leverage current, historical and external information like point-of-sale data from a single, enterprise-wide data repository.)

2. STATEMENT OF THE PROBLEM

Studies have shown that Blockchain, artificial intelligence, cloud computing, and robotics improve overall efficiency, accuracy, and supply chain collaboration. Blockchain is a specific type of database. As far as supply chains are concerned, several exchanges happen where parties have no reason to trust each other. Blockchain technology can be used and duplicate, or error-prone transactions can be reduced. Different types of information can be stored on a blockchain, but the most common use has been as a ledger for transactions.

Gaps in the existing supply chain are an equally big challenge. Following are the key areas of concern:

- Some problems are related to a lack of real-time stock visibility across all levels.
- There is improper reporting when it comes to records that are related to OTC drugs that have been returned.
- There seem to be instances of improper stock register maintenance.
- There seems to be a situation where stock levels have not been maintained at the recommended levels to avoid shortages.
- There seem to be instances of a cross supply of OTC drugs without proper intimation to the select store.
- It seems as if, in several cases, the primary health centres retain OTC drugs on session days to maintain good stocks when undersupplied.
- They seem to be several gaps due to which actionable data is either not produced or is meaningless.
- To improve the overall visibility in the supply chain and make reliable forecasts, there needs to be a proper distribution alignment with the demand.
- Artificial intelligence-powered automation can save several OTC drugs from being wasted, and distribution schedules can be maintained so that people do not miss their doses.
- Overall, the supply chain must be well integrated to predict shortfalls, re-route shipments and enable real-time tracking.

3. REVIEW OF LITERATURE

Patidar A, et.a (2021) performed a study entitled **" Sustainable Supply Chain Research and Key Enabling Technologies: A Systematic Literature Review and Future Research Implications"**. The concept of sustainability is becoming a buzzword these days. Incorporation of sustainability into Supply Chain Management is reviewing great attention from the wide range of industries in recent years. It is also an important study to review the impact of enabling technologies like Blockchain technology, Internet of Things (IoT), Big data, AR and VR-Immersive technologies, Artificial Intelligence on the economic, social and environmental aspects of Supply Chain performance. The importance of this study has attracted many academic researchers to publish their research in journals and proceedings, where discussion is about research progression both quantitatively and qualitatively. Following the progression, the study focuses on the review of key enabling technologies and sustainable supply chain providing insight into the development. Besides providing the insights of the progression this study also focuses on application areas of technologies along with its acceptance. Study presents a Systematic Literature review for showing the insights of key enabling technologies and sustainable supply chain along with the toppers of the research in terms of top authors, top journals, top research areas and top countries conducting this research thereby concluding the current status of the technology applications in sustainable supply chain and elaborating future research implications.[3]

Alicke, K. et.al. (2017) have presented a report entitled **"Supply Chain 4.0 in consumer goods (Mckinsey & Company, 1-11)".** The report states that over the last 30 years, supply chain has undergone a tremendous change. What was once a purely operational logistics function that reported to sales or manufacturing and focused on ensuring supply of production lines and delivery to customers has become an independent supply-chain management function that in some companies is already being led by a CSO—a chief supply-chain officer. The focus of the supplychain management function has shifted to advanced planning processes, such as analytical demand planning or integrated sales and operations planning (S&OP), which have become established business processes in many companies, while operational logistics has often been outsourced to third-party logistics providers. The supply-chain function ensures that operations are well-integrated, from suppliers through to customers, with decisions on cost, inventory, and customer service made from an end-to-end perspective rather than by each function in isolation. Digitization creates a disruption and requires companies to rethink the way they design their supply chain. At the same time, customer expectations are growing: recent online trends have led to growing service expectations combined with much more detailed orders. Also, a definite trend toward further individualization and customization is driving strong growth of and constant changes in the SKU portfolio. The online-enabled transparency and easy access to a multitude of options regarding where to shop and what to buy drive the competition of supply chains. Overall, the report focusses on the impact of Supply Chain 4.0. It also explains what is Supply Chain 4.0.[4]

Mengoli C. (2007) performed a study entitled **"Pharmaceutical Trading and Distribution Channels: The European Business of OTC Drugs (The expansion of the Italian brand "Menarini")"**. The authors discuss the vertical and the horizontal integration of the pharmaceutical market. The authors state that this has happened as aresults of the several changes, which have increased the amount of investments made in the sector. European companies are achieveing economies of scale, economies of scope, and several mergers and acquisitions are happening. Also the old model of pharmaceutical supply chain in Europe has been invested by a gradual change of bearings. The EU business of medicines

is turning towards the Direct-to-Pharmacy model, which is going to be the latest new trend of the whole sector. As a matter of fact every day more and more final consumers are relying on the supply chain to deliver the medicines they need across the Europe. The liberalization is affecting the whole sector especially of OTCs (Over the Counter drugs), with large consequences for the wholesaler margins and VAT. The EU laws, the parallel trade and the EU enlargement are playing an other strategic role in order to understand that phase of bedding. Overall, the study is more focussed on the various factors that affect the supply chain of OTC medicines in Europe. However, the study is majorly based on secondary data.[5]

King & Zhang (2007) performed a study entitled **"Applying RFID to Secure the Pharmaceutical Supply Chain".** The authors discuss how RFID can be applied to increase integrity and confidence in the pharmaceutical supply chain. According to the authors, secured pharmaceutical supply chain will increase integrity, improve consumer confidence, and aid regulators in tracking pharmaceutical products, thus producing a "pharmaceutical drug pedigree". The authors provide an analysis of the pharmaceutical supply chain, and propose a security model for the system. Overall, the study indicates that new technologies were being applied to Supply chain managament with the intention of increasid the efficiency and reliability of the supply chain. However, the study lays overemphasis only on RFID technology. [6]

Masood & Syed (2015) performed a study entitled **"Preserving Efficacy of Temperature Sensitive Medicines–Logistics Management in Pharmaceutical Supply Chain"**. The authors state that protecting the efficacy of temperature-sensitive drugs is a real challenge especially for the countries with hot climates. Over-the-counter medicines have recommended storage-temperature of around 20-30 °C, while ambient temperature in most metropolitan areas of Pakistan reach around 40-50 °C in summers, even under the shade. Other temperature-sensitive medicines require storage at around 4-8 °C. A reputation of spurious drugs due to mismanagement with regard to transport and storage also goes contrary to the interests of the pharmaceutical sector. This research investigates the preservation and storage of temperature-sensitive medicines in its specialized supply-chain (referred to as "cold chain") and finds that while the import of active ingredients is rather well managed and controlled with storage at within the desired temperatures; the distribution-chain needs to be more adaptive of the standards in-order to better preserve efficacy of the medicines. Nevertheless, long hours of power black-outs (a common occurrence in Pakistan and other under-developed nations) further guarantee the deterioration of temperature-sensitive medicines stored at the chemist-shops. It is therefore, recommended that temperature-sensitive medicines should only be dispensed from stores that have standby-power. Overall, the study deals with the aspect of temperature and lays overemphasis on that aspect. The attempt made by the researchers is relevant in terms of issues related to temperature. However, the study was done in Pakistan, which is an under-developed country. 2.5 to 11 percent of the total population of Pakistan are beggars.[7] Thus, the study does not focus on the latest aspects of Supply Chain 4.0. In a country of terrorists and/ or beggars, a valid research cannot be performed and even if any research is done, especially that relates to the supply chains, will not yeild results that can be considered valid.[8]

Yang et. al. (2017) performed a study entitled **"Hardware-Enabled Pharmaceutical Supply Chain Security".** The authors opine that pharmaceutical supply chain is the pathway through which prescription and over-the-counter (OTC) drugs are delivered from manufacturing sites to patients. Technological innovations, price fluctuations of raw materials, as well as tax, regulatory, and market demands are driving change and

making the pharmaceutical supply chain more complex. Traditional supply chain management methods struggle to protect the pharmaceutical supply chain, maintain its integrity, enhance customer confidence, and aid regulators in tracking medicines. To develop effective measures that secure the pharmaceutical supply chain, it is important that the community is aware of the state-of-the-art capabilities available to the supply chain owners and participants. In this article, the authors have presented a survey of existing hardware-enabled pharmaceutical supply chain security schemes and their limitations. They also highlight the current challenges and point out future research directions. This survey however, is more focussed only towards the aspect of security and safety.[9]

Narsimha P et al. (2021) states that the maritime industry that accounted for more than 90% of the international trade was badly affected due to the pandemic outbreak. The study is about the impact of the Covid 19 pandemic on the major ports in India. The researchers have made a sincere attempt to identify different patterns for quantitative performance data before and during the Covid 19 pandemic. The study has inculcated various views from experts about the response, recovery, preparedness and the overall impact for the maritime-related sector in India. The authors suggest a negative impact of Covid 19 on the maritime industry, and the firms need to develop future strategies so that they can survive in the long run. The study's findings suggest that several maritime strategies need to be changed to enhance the overall resilience of the supply chain and initiate business recovery from the maritime context.[10]

Queiroz, M. M. et al. (2020) have studied **the adoption of blockchain in operations and supply chain management.** According to the authors, the operations and supply chain management fields are changing as new technologies are adopted. Due to the rapid emergence of disruptive technologies and the emergence of cutting-edge techniques, operations and supply chain management systems are striving to take advantage of such innovations. However, the authors also state that there are several advantages challenges in achieving this particular feat. The study focuses on adopting blockchain technology and barriers in the Brazilian operations supply chain management context. The study's findings revealed that social influence, trust, and effort expectancy are the most critical constructs directly impacting locked-in technology adoption.[11]

Khaled, S. et al. (2020) performed a study entitled **"blockchain-based supply chain traceability for Covid 19 PPE"**. The authors state that the Covid 19 pandemic affected a majority of the industries. The pandemic exposed systemic vulnerabilities in emergency preparedness, problems and supply chain management and mitigation of risk. During the pandemic, there was an increased demand for personal protective equipment. There was a huge demand pressure on the PPE production. The authors have underlined the lack of information visibility problems and the inability to precisely track product and supply chain. According to the authors, blocking technology can ensure a transparent, secure, and safe data exchange among the various stakeholders belonging to a particular supply chain. The authors have discussed the advantages of adopting blockchain technology to track and manage personal protection equipment products in the supply chain. The authors talk about security, traceability, decentralize control and auditable time-stamped transactions. The authors have suggested using a blockchain-based approach using smart contracts to transform supply chain operations of personal protective equipment. The study was inspired by the Gen assembly, which is

currently used by Ethereum smart contracts. The authors have performed an in-depth analysis of the security and cost incurred by the stakeholders in the supply chain. The study's findings revealed that using a blockchain-based solution for personal protective equipment supply chains is viable economically and provides a secure, transparent, trusted and streamlined mode of communication among the various stakeholders in the supply chain.[12]

Baozhuang et.al. (2021) performed a study entitled **"Incentive alignment for blockchain adoption in medicine supply chains".** The authors state that in recent years, blockchain technology has been increasingly adopted in OTC medicine supply chains, enabling customers to track the entire process from raw material purchasing to finished medicine distribution. This improves the brand image and hence expands the market. With the use of blockchain, information transparency can be achieved because data are stored immutably and safely in a distributed database that is accessible by all supply chain members. The authors investigate the supply chain members' incentive alignment opportunities towards the adoption of blockchain technology. For achieiving this objective, the authors consider a two-stage supply chain comprising two medicine manufacturers and a common retailer that has more accurate demand information than the manufacturers have. The authors find that, interestingly, the retailer has incentives to participate in blockchain when the manufacturers' competition is mild and the demand variance is low. The authors further investigate the impact of blockchain on total surplus and customer surplus and find that the adoption of blockchain always benefits customers and society; therefore, blockchain can be particularly useful for social goods such as OTC medicine.[13]

RESEARCH GAP:

In this study, the literature has been used to understand how the current situation looks in the areas of interest for the study and to discover the theoretical perspectives that are relevant for the study.

The following research gaps were identified from the above literature referred:

1. Researchers have performed various studies that speak about supply chain sustainibility. However, there is very less research that provides practical information regarding the various challenges the OTC drugs supply chain has faced in India. Most of the studies that have focused on the problems of the supply chain of OTC medicnines have relied on secondary data.
2. Various researchers have studied drug shortages and have tried to analyze the various causes and implications. However, these studies focus too much on the impact of the Covid 19 Pandemic. It should be noted that the pandemic is temporary. This means that over the period, the research done will become obsolete very soon. Another reason why the current studies do not make sense is that very few studies have made an attempt to understand the impact of Sypply Chain 4.0 on the overall efficiency of the supply chains (OTC drugs especially).

3. No such study has been specifically done for the Mumbai Metropolitan Region (MMR). This current study concentrates on the population in MMR and the overall framework of the distribution of OTC medications in the state.
4. The current study aims to to study the impact of supply chain 4.0 on predictive business intelligence. No such study has been conducted for OTC medicines for the MMR.
5. Research regarding the implementation of blockchain for managing the supply chain for OTC medicines in the MMR does not seem to exist.
6. Overall, the research performed by others is quite general, and the scope of the existing studies seems to be vague. However, the current research proposes to focus on the problems and barriers faced by the supply chain of OTC drugs and includes building a model that could increase the overall efficiency of the supply chain for the supply of OTC drugs.

4. THEORETICAL CONSTRUCT

A construct refers to a concept or characteristic that cannot be directly observed but measured by other associated indicators. Constructs can be characteristics of individuals, such as intelligence, obesity, job satisfaction, or depression; they can also be broader concepts applied to organizations or social groups, such as gender equality, corporate social responsibility, or freedom of speech.[14]

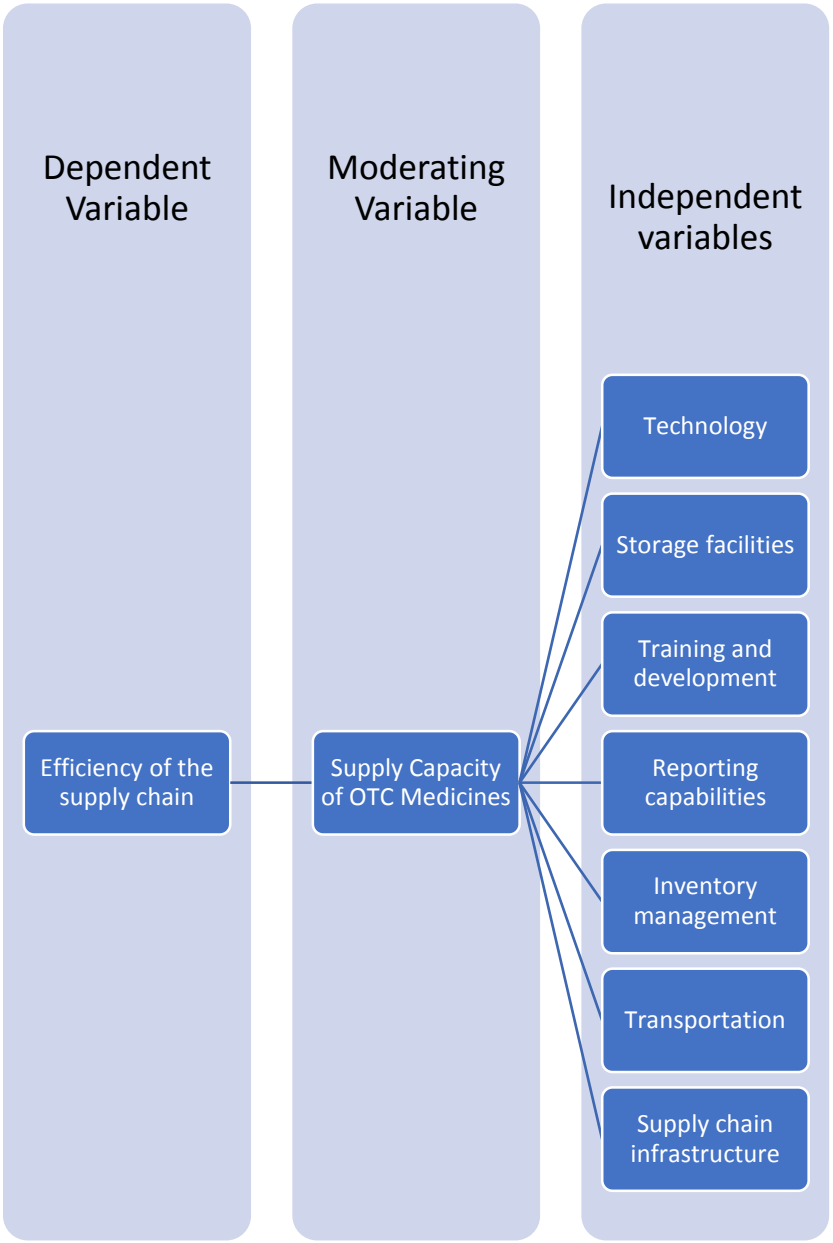
The current study uses a systems approach. The systems approach was used as it is more pragmatic. Rather than searching for probing for the absolute truth, the researcher proposes solutions that can impact the actual supply chain and distribution system for the sypply of OTC drugs in India. The researcher proposes identifying the various parts of the system and establishing a causal relationship by creating an understanding of the case study (Gammelgard 2004).[15]

The current study investigates the various challenges in the supply chain for OTC medicines in MMR. This particular study propopses to include various aspects, including drug administration, information systems, human resources in the sypply chain, personnel who manage storage facilities, transportation and logistics of OTC medicines and their procurement.

The current study also uses an analytical approach that is closer to the reality of things. The study proposes to focus on explaining reality as a single entity to identify the patterns without distortions. The study tries to establish a cause and effect relationship and uses a quantitative approach. This is because the study would analyze the responses of the pharmaceutical retailers (Unorganizaed) and the final consumers. This would be done to understand the various challenges faced by the supply chain and distribution systems for the OTC medicines in India.

The study would make a sincere attempt to identify the benefits of the implementing of the Supply Chain 4.0, and the various challenges that are faced by companies who manufacture OTC medicines while implementing the Supply Chain 4.0 routines.

IDENTIFICATION OF VARIABLES



A. Dependent variable:

1. **Efficiency of the supply chain**:

This is the variable that is dependent on factors that have been mentioned in the list of independent variables. The efficiency of the supply chain is reflected in the following aspects:

1. Lack of shortages

2. Minimal wastage

3. Level of adherence to the planned schedules

B. Moderating variable:

1. **Supply capacity of OTC Medicines**:

The moderating variable is the supply capacity of OTC drugs. This is because the supply chain's scope to perform accurately is only after the OTC drugs are manufactured plentifully. If the demand and supply of OTC drugs are not properly aligned, one cannot blame the supply chain completely. Therefore, the overall capacity of supply of OTC drugs is one of the crucial variables that would ensure a proper supply of OTC drugs on a timely basis.

C. Independent variables:

1. **Technology**: various innovative technologies can be used to manage supply chain and logistics. Some of the technologies have already been discussed in the earlier part of the proposal. These technologies include cloud computing, artificial intelligence, blockchain system, robotics et cetera.

2. **Storage facilities**: after being manufactured, the OTC drugs have to be stored in a secure storage facility that can maintain the required parameters essential to store the medicines properly. If the OTC drugs are improperly stored, they can go bad. This will lead to an increase in wastage is and will indirectly affect the overall efficiency of the supply chain.

3. **Reporting capabilities**: when a particular system generates real-time reports, it certainly contributes to the overall efficiency of the supply chain. However, if there is a lag in the reporting system, it can disrupt the flow of the entire supply chain. Therefore, reporting capabilities are an essential element determining a particular supply chain's overall success or efficiency.

5. **Inventory management**: without proper inventory management, a pharmacy retail outlet (unorganizaed) cannot ensure that there is no shortage of OTC drugs at a particular time. Therefore, inventory management is one of the most critical variables that would decide the overall efficiency of the supply chain.

5. OBJECTIVES OF THE STUDY

1. To find out the various factors that influence the efficiency of the supply chain of over the counter drugs especially during the Covid 19 pandemic.
2. To observe the impact of advanced supply chain analytics on the supply chain operations of pharmaceutical companies selling over-the-counter medicines.
3. To study the key aspects that have changed in the distribution ecosystem due to the digitisation of the supply chain with the application of supply chain 4.0.
4. To find out whether the application of supply chain 4.0 has influenced command and control of dynamic real-time partnership between pharmaceutical companies (manufacturing OTC medicines) and their suppliers.

5. To study the efficiency of the cloud-based dashboard, AR and VR applications in terms of end to end visibility and traceability.
6. To study the impact of supply chain 4.0 on the last mile delivery of over-the-counter drugs.
7. To study the impact of supply chain 4.0 on predictive business intelligence

(Note: Predictive business intelligence means using artificial intelligence, machine learning, asset tracking and social media intelligence applications to produce accurate, statistics-based demand forecasts that leverage current, historical and external information like point-of-sale data from a single, enterprise-wide data repository.)

6. Hypothesis

H1. Application of supply chain 4.0 has a positive impact on predictive business intelligence of Pharma companies that make OTC drugs.

Ho: Application of supply chain 4.0 has a positive impact on predictive business intelligence of Pharma companies that make OTC drugs.

Ha: Application of supply chain 4.0 has no impact on predictive business intelligence of Pharma companies that make OTC drugs.

H2: OTC drugs get wasted only because of the inefficiency in the supply chain and distribution system.

Ho: OTC drugs get wasted not only because of the inefficiency in the supply chain and distribution system.

Ha: OTC drugs get wasted only because of the inefficiency in the supply chain and distribution system.

H3: The technology element has a considerable influence on the overall efficiency of OTC drugs' supply chain and distribution system.

Ho: The technology element does not influence the overall efficiency of OTC drugs' supply chain and distribution system.

Ha: The technology element has a considerable influence on the overall efficiency of OTC drugs' supply chain and distribution system.

H4: There are various inefficiencies in the inventory management system that is being used for the purpose of storing and distributing OTC drugs.

Ho: There are no inefficiencies in the inventory management system that is being used for the purpose of storing and distributing OTC drugs.

Ha: There are various inefficiencies in the inventory management system that is being used for the purpose of storing and distributing OTC drugs.

H5: The application of supply chain 4.0 has influenced command and control of dynamic real-time partnership between pharmaceutical companies (manufacturing OTC medicines) and their suppliers.

Ho: The application of supply chain 4.0 has not influenced command and control of dynamic real-time partnership between pharmaceutical companies (manufacturing OTC medicines) and their suppliers.

Ha: The application of supply chain 4.0 has influenced command and control of dynamic real-time partnership between pharmaceutical companies (manufacturing OTC medicines) and their suppliers.

H6: The cloud-based dashboard, AR and VR applications enable end to end visibility and traceability.

Ho: The cloud-based dashboard, AR and VR applications do not enable end to end visibility and traceability.

Ha: The cloud-based dashboard, AR and VR applications enable end to end visibility and traceability.

7. RESEARCH METHODOLOGY

1) Research Design:

Exploratory research is defined as research used to investigate a problem that is not clearly defined.[16] The current study investigates the various supply chain and distribution management problems in the supply of OTC medicines in MMR.

However, the major limitation of exploratory research is that it does not provide conclusive results. This is where the researcher proposes to increase the descriptive and analytical capabilities of the research. Descriptive research classifies, describes, compares, and measures data. Meanwhile, analytical research focuses on cause and effect. The researcher proposes to consider a pragmatic approach to this research. The current research proposes to establish a cause-and-effect relationship between the dependent, independent and moderating variables. The researcher proposes that the current research would make several comparisons and classify

data to get the correct measure of the overall efficiency of the supply chain and distribution system of OTC medicines in the state of MMR.

2) **Data Collection**: Both primary and secondary data collection methods will be used.

a) Primary data collection method and structured questionnaire will be used, and data collection techniques will assist in bringing the real insight to understand the research problem at various levels

Proposed classes of respondents:

The primary data will be collected through a structured questionnaire from the following respondents.

1. The proprietors of the unorganizaed pharmacy retail outlet.
2. The wholesalers of the related OTC drugs.
3. Employees of the Pharma Companies that have offices in MMR. (Administrative/ Maegerial Staff from the SCM/ Logistics/ Procurement/ Distribution function.)

b) Secondary data will be collected from allied sources like the Internet, newspapers, reference books, government portals etc.

3) Questionnaire Design: The questionnaire will be designed by using both measurement and rating scales. The measurement scales include nominal scale, ordinal scale and interval scale. A nominal scale has been used to understand the profile of the respondents like the type of bank, age, experience, marital status, education, gender and salary.

The ordinal scale is a ranking scale used to rank the attributes for digital transformation. The Interval scale is used as an attitude measurement scale on 1 -5, 1 = Extremely unimportant to 5 = Extremely important. In this study, an interval scale is used to determine the importance of digital transformation through change and innovation. The Likert rating scale is used as a rating scale to indicate the agreement or disagreement on a series of statements related to change, innovation, and digital transformation on 1 – 5, 1 being strongly disagreed and five being strongly agreed.[17]

4) **Sample Design**:

a) Total Population: The population for this study is large and unknown. However the population is finite.

b) Sample Size:

- The researcher proposes to include about 300-400 retailers and about 100-200 wholesalers (unorganized).

  The researcher proposes administering the structured questionnaire to at least 150 employees from 30 pharmaceutical companies who manuafacture the OTC drugs that fall under the perview of the current research by using both Measurement scales and rating scales on scale of 1 to 5. As mentioned earlier, Employees of the Pharma Companies that have offices in MMR. (Administrative/ Manegerial Staff from the

SCM/ Logistics/ Procurement/ Distribution function) would be considered for the purpose of the study.

c) Sampling Unit: Retailers, Wholesalers, Employees of the pharma Companies.
d) Sampling Technique: A combination of probabilistic and non-probability sampling techniques will be used.
e) Sampling Method: In this study Snowball sampling and Convenient sampling (non probability sampling) will be used to select the sample. By using snowball sampling the information about the OTC manufacturers from varios zones can be identified. After the references obtained about OTC manufacturers, convenient sampling will be used to access the information about the distribution of OTC medicines.
Since the study covers the Mumbai Metropolitan region, the researcher proposes to divide the entire region into four zones. These four zones will represent the strata from where the respondents will be chosen. This method can be used to make a list of pharmaceutical retailers at random and using a random number generator, the researcher can select the required number of retailing outlets so that the researcher can approach the proprietors or managers of pharmaceutical retail stores strategically. However, as far as the wholesale outlets are concerned, the researcher may have to follow convenience sampling depending on the availability of the wholesalers. The same thing as applicable to the employees of the pharmaceutical companies. The researcher may have to use convenience sampling or snowball sampling to gain the responses from at least two classes of respondents. As far as possible, the researcher proposes to implement the element of randomness in sampling to ensure reliable results.

5) **Statistical Tools**:
The following statistical tools have been used to study the impact of change and innovation on the digital transformation of private and foreign banks in Mumbai like

1. Chi-Square
2. Pearson Correlation
3. Multiple Regression Analysis
4. Factor Analysis
5. Reliability Analysis
6. Structural Equation Modelling (SEM)
7. Simple Percentage Method

1) Chi-Square is called a goodness-of-fit test. It is used to test how observed frequencies differ from expected frequencies. The Chi-Square test between two variables has been used to find out the symmetric association between the variables.

2) Pearson Correlation is a bivariate analysis used to determine the degree of association between the variables. It is also used to determine the strength and relationship between the variables. It is denoted by r called as Correlation Coefficient. The value ranges r from +1 to -1[+1 indicates positive correlation, -1 indicates negative correlation]. If the value of r is

between [0.75 to 1 (it is high association), 0.5 to 0.74 (moderate association), less than 0.5 (low association].

3) Multiple Regression Analysis has been used to test the effect of independent variables on the dependent variable. This allows researchers to assess the strength of the relationship between an outcome (the dependent variable) and several predictor variables and the importance of each of the predictors to the relationship, often with the effect of other predictors statistically eliminated.

4) Factor Analysis is a multivariate analysis used to test the variables simultaneously. It is used in data reduction and data summarization.

5) Reliability Analysis has been used to test the internal consistency among the variables. Factor Analysis is a multivariate analysis used to test the variables simultaneously.

6) Structural Equation Modeling (SEM) has been used to simultaneously test the equations of multiple regressions.

7) Simple Percentage Method has been used where a percentage is used to determine the relationship between the data series.

8. SIGNIFICANCE OF THE STUDY

The key factors propelling the growth of the Indian over-the-counter drugs market are the shift in consumer attitude toward self-medication, product innovations, and inclination of pharmaceutical companies toward OTC drugs from prescription (RX) drugs.

The current study focuses on the various challenges that are being faced by the supply chain for OTC drugs. The study also aims to make certain recommendations that would include modifications to be made in the

1. Manufacturing and procurement of OTC drugs and materials that are required for their production.

2. Recommendations related to building more capacity and maintaining infrastructure so that the concept of supply chain 4.0 can be used to manage the logistics of the entire campaign.

3. The study would analyse the impact of the application of supply chain 4.0 on the predictive business intelligence of the pharma companies.

9. SCOPE OF THE STUDY

The scope of the study is quite wide as it covers the following areas:

1. The geographical scope of the study extends to the entire MMR region.
2. The study also digs deep into the various governmental policies and critically evaluates the entire supply chain of OTC medicines.
3. The stuy covers the broad specturn under "Predictive business intelligence". This implies the usage of artificial intelligence, machine learning, asset tracking and social media intelligence applications to produce accurate, statistics-based demand forecasts that leverage current, historical and external information like point-of-sale data from a single, enterprise-wide data repository.

10. LIMITATIONS OF THE STUDY

1. The study has a geographical limitation as it covers only the MMR region.
2. The study primarily focuses on only the aspects of supply chain and distribution management of specific OTC drugs. It is not possible to cover all categories of OTC medications (herbal/ homeopathic OTC medicines for example).
3. The study does not include the impact of political influences on supply chains.
4. The number of respondents covered can be increased. However, it is only possible if the research is funded. Since this is a PhD thesis and purely academic, the study suffers from financial limitations. Due to budget constraints for the research, the sample size may reduce based on budgetary and topological and availability constraints. It would, however, be sufficient to encompass a fair and accurate indicator of the target population.

11. TENTATIVE CONCLUSIONS

- There are various challenges in managing the supply chain and logistics for the distribution of related OTC drugs.
- Application of supply chain 4.0 has a positive impact on predictive business intelligence of Pharma companies that make OTC drugs.
- OTC drugs are getting wasted not only because of the inefficiency in the supply chain and distribution system.
- The technology element has a deep influence on the overall efficiency of the supply chain and distribution system for OTC drugs.
- The various inefficiencies, on the human resource level and technology level, the real-time monitoring of stock and storage temperature of the OTC drugs kept in multiple locations across the state is challenging.
- There's a scope to bring about several improvements to implementing new technologies like blockchain, the Internet of things and other database management systems to increase the overall efficiency of the supply chain and distribution of OTC drugs in MMR.

12. REFERENCES

[1] https://www.expresspharma.in/otc-healthcare-products-a-growth-area-for-india-pharma-inc/ Retrieved on 3.9.2021.

[2] https://www.mckinsey.com/business-functions/risk-and-resilience/our-insights/covid-19-implications-for-business Retrieved on 3.9.2021.

[3] Patidar, A., Sharma, M., Agrawal, R., Sangwan, K. S., Jamwal, A., & Gonçalves, M. (2021, June). Sustainable Supply Chain Research and Key Enabling Technologies: A Systematic Literature Review and Future Research Implications. In International Conference Innovation in Engineering (pp. 305-319). Springer, Cham.

[4] Alicke, K., Rexhausen, D., & Seyfert, A. (2017). Supply Chain 4.0 in consumer goods. Mckinsey & Company, 1-11.

[5] Mengoli, C. (2007). Pharmaceutical Trading and Distribution Channels: The European Business of OTC Drugs (The expansion of the Italian brand "Menarini").

[6] King, B., & Zhang, X. (2007). Applying RFID to secure the pharmaceutical supply chain. International Journal of Security and its applications, 1(2), 71-84.

[7] https://www.thenews.com.pk/print/660213-child-begging#:~:text=As%20per%20current%20estimates%20there,to%20be%20on%20the%20rise.

[8] Subzwari, M., & Nasir, S. Z. (2015). Preserving Efficacy of Temperature Sensitive Medicines–Logistics Management in Pharmaceutical Supply Chain. South Asian Journal of Management, 9(1), 1-9.

[9] Yang, K., Shen, H., Forte, D., Bhunia, S., & Tehranipoor, M. (2017). Hardware-enabled pharmaceutical supply chain security. ACM Transactions on Design Automation of Electronic Systems (TODAES), 23(2), 1-26.

[10] Narasimha, P. T., Jena, P. R., & Majhi, R. (2021). Impact of COVID-19 on the Indian Seaport Transportation and Maritime Supply Chain. Transport Policy.

[11] Queiroz, M. M., Fosso Wamba, S., De Bourmont, M., & Telles, R. (2020). Blockchain adoption in operations and supply chain management: empirical evidence from an emerging economy. International Journal of Production Research, 1-17.

[12] Omar, I., Debe, M., Jayaraman, R., Salah, K., Omar, M., & Arshad, J. (2020). Blockchain-based supply chain traceability for COVID-19 PPE.

[13] Niu, Baozhuang, Jian Dong, and Yaoqi Liu. "Incentive alignment for blockchain adoption in medicine supply chains." Transportation Research Part E: Logistics and Transportation Review 152 (2021): 102276.

[14] Midgley, D. F., & Dowling, G. R. (1978). Innovativeness: The concept and its measurement. Journal of consumer research, 4(4), 229-242.

[15] Gammelgaard, B. (2004). Schools in logistics research? A methodological framework for analysis of the discipline. International Journal of Physical Distribution & Logistics Management.

[16] Durrheim, K. (2006). Research design. Research in practice: Applied methods for the social sciences, 2, 33-59.

[17] Singh, Y. K. (2006). Fundamental of research methodology and statistics. New Age International.